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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,098	04/16/2004	Ma. Teresa Y. Tan	DIZ-5	9265

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EXAMINER	
CLAYTOR, DEIRDRE RENEE	

ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,098	TAN ET AL.	
	Examiner	Art Unit	
	Renee Claytor	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed on 7/16/2007 is hereby acknowledged. Applicant's arguments have been fully considered and are not found persuasive.

In particular, Applicant's argue over the 35 USC 103 rejection that Khan et al. requires a double layered film-coat for the cefuroxime axetil tablet of his invention to rupture in more than 40 seconds without gelling of the cefuroxime axetil and it would not be obvious to try to use a single-layered capsule. Applicants further argue that Amey et al. does not cure the deficiencies of Khan et al. and only teaches a process for encapsulation of caplets in a capsule by cold-shrinking. Applicants assert that their tablet-in-a-capsule does not result in gel formation of cefuroxime axetil, even if the rupture time is longer than 40 seconds and that the prior art (referring to Deutsch et al.) teaches the rupture time cannot exceed forty seconds. Applicants further argue that Wang does not cure the above deficiencies.

In response to the above arguments, it is pointed out that claim 1 reads on a composition that comprises a core tablet of cefuroxime axetil inside a capsule, and the capsule having a rupture time of more than sixty seconds. Khan et al. was used for the clear teaching of cefuroxime axetil in a tablet core and also teaches that the composition of the invention has a rupture time between 45-240 seconds which reads on the instant claimed invention. The invention of Khan is intended to provide better dissolution because of the delayed release of cefuroxime axetil. Further, Amey et al. teaches that the encapsulation of caplets in a capsule is performed to provide a dosage form that is more easily swallowed which provides a motivation to encapsulate the core

tablet of Khan et al. Though Amey et al. teach that their process is by a cold-shrinking method and Applicant's argue that their method is different is of no consequence to the present claims because they are drawn to a pharmaceutical composition. Further, arguments were put forth in reference to a reference by Deutsch et al. This reference was not used in the rejection and is not being addressed herein. Accordingly, the prior art does teach a composition of cefuroxime axetil in a core tablet and rupture times of 45-240 seconds and there is also a teaching that encapsulation of caplets in a capsule is beneficial. Further, Wang teaches a clear need for capsules from vegetable sources and provides a motivation that these types of capsules are in demand by consumers.

The following rejections are given below for Applicant's convenience.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-12 and 15-16 are rejected under 35 U.S.C. 103(a) as being obvious over WO 02/43707 to Khan et al, published June 6, 2002, in view of U.S. Patent No. 6,080,426 to Amey et al, issued June 27, 2000.

Khan et al. teaches an oral pharmaceutical form of cerufoxime axetil where the drug is contained in a tablet core and is coated with a double layered film coat (see abstract, in particular.) Khan et al. teaches that the first film coat masks the bitter taste of the cefuroxime axetil while the second film coat delays the rupture time beyond 40 seconds (see abstract, in particular), and even teaches that the rupture time can be between 45-240 seconds (see page 4, second full paragraph, in particular.) Khan et al. teaches that the delayed rupture time is desirable because patients find it easier to swallow dosage forms that have a longer rupture time (see paragraph bridging pages 3-4, in particular.)

Khan et al. does not specifically teach that the tablet has a rupture time of more than 60 seconds, as recited in claim 1. However, as Khan et al. teaches that the film coat can be selected to provide a rupture time of from 45-240 seconds, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the rupture time, according to the guidance provided by Khan et al, to provide a composition having desired administration properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claims 6-8, Khan et al. furthermore teaches that the tablet can contain from 2 to 15% by weight of disintegrant, and that an effective amount of disintegrant can

be provided to achieve the desired disintegration of the tablet (preferably within 1 minute) after rupture of the film (see page 5, fourth full paragraph, in particular.)

Regarding claims 9 and 15-16, Khan et al. teaches that the disintegrant can be starch, sodium starch glycolate, croscarmellose sodium and others (see page 5, fourth full paragraph, in particular.) Regarding claim 10, Khan et al. teaches that the cefuroxime axetil is desirably in the amorphous form (see page 1, third full paragraph, in particular.)

Khan et al. does not teach providing the specific % weight ranges of disintegrant in the caplet as recited in claims 6-8. However, Khan et al. teaches providing a range of disintegrant that is overlaps with the range recited in claim 6, and that is very close to the ranges recited in claims 7-8, with the range recited in claim 7 having a lower limit (20%) that is only 5% greater than the preferred upper limit (15%) specified by Khan et al. Khan et al. furthermore teaches of the desirability of providing an effective amount of disintegrant in the tablet to disintegrate the tablet rapidly upon rupture of the film coating. Thus, one of ordinary skill in the art at the time the invention was made would have found it obvious to optimize the % weight of disintegrant included in the tablet to provide the desired rate of disintegration of the tablet. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Khan et al. does not specifically teach providing the tablet in a capsule or the composition of the capsule.

Amey et al. teaches that the encapsulation of caplets in a capsule can be performed to provide a dosage form that is more easily swallowable than uncoated caplets (see column 1, lines 15-28, in particular) and that does not exhibit the disadvantageous associated with coated caplet forms, such as non-uniformity of the coating (see column 1; lines 28-50, in particular.) Thus, Amey et al. teaches that encapsulated capsule forms can be provided as an improved alternative to coated or non-coated capsules.

Regarding claims 3-5, Amey et al. teaches a process for encapsulation of caplets in a capsule comprising providing empty capsule parts, filling at least one of said capsule parts with one or more caplets, putting said capsule parts together, and treating the combined parts by cold shrinking (see abstract, in particular.) Amey et al. teaches that a specifically preferred version has a clearance of the capsule shell and caplet in the range of from about 0 to about -0.5 mm, meaning that the caplet is compressed in the capsule (see column 2, lines 50-54, in particular.) Thus, as Amey et al. teaches a caplet and capsule have less than zero clearance between each other, it follows that the diameter of the caplet taught by Amey et al. must be greater than or equal to 80% of the internal diameter of the capsule taught by Amey et al.

Regarding claims 11-12 and 14, Amey et al. teaches that suitable materials for the capsule can include gelatin, hydroxypropyl methylcellulose or starch (a polysaccharide) (see column 3, lines 18-34, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have been motivated to substitute at least one of the film coats of the greater than 60 second rupture time cerufoxime axetil tablet composition of Khan et al, with a surrounding capsule as taught by Amey et al, because Amey et al. teaches that encapsulation of caplets and tablets can advantageously be performed instead of coating such tablets, and thus teaches the interchangeability of the methods. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to provide the capsule of Amey et al. in place of at least one of the film coats of Khan et al., with the expectation of providing a suitable form for the delayed rupture and release of cerufoxime axetil.

Claims 13-14 are rejected under 35 U.S.C. 103(a) as being obvious over WO 02/43707 to Khan et al, published June 6, 2002, in view of U.S. Patent No. 6,080,426 to Amey et al, issued June 27, 2000, as applied to claims 1-12 and 15-16 above, and further in view of U.S. Patent No. 6,482,432 to Xiping Wang, issued November 19, 2002.

Khan et al. and Amey et al. are applied as discussed above, and render obvious providing a cefuroxime axetil tablet inside a capsule that ruptures in greater than 60 seconds. Khan et al. and Amey et al. do not specifically teach that the capsule is made of vegetable or plant-based cellulose.

Wang teaches that there is consumer demand for capsules made from vegetable sources, such as vegetable gelatin or hydroxypropyl methylcellulose (see column 1, lines 52-60, in particular.) Wang also provides examples of therapeutic ingredients being encapsulated in cellulose derivative capsules or vegetable cellulose capsules (see column 2, lines 55-61, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have been motivated to provide a capsule made of vegetable based cellulose in the encapsulated caplet dosage form of Khan et al. and Amey et al, with the expectation of providing a capsule that is suitable for encapsulating therapeutic ingredients and that is in demand by consumers.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is 571-272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor